

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

DOUGLAS J. HORN and CINDY HORN,

Civil Action No. X

Plaintiffs,

15-cv-701 (FPG)(MJR)

-against-

MEDICAL MARIJUANA, INC.;
DIXIE ELIXIRS AND EDIBLES;
RED DICE HOLDINGS, LLC; and
DIXIE BOTANICALS

Defendants.

X

PLAINTIFFS 'MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S 60(b) MOTION FOR RELIEF FROM AN ORDER

Dated: New York, New York
September 15, 2020

Respectfully submitted,

BENJAMIN ♦ HART, P.C.
Attorneys for Plaintiff HORN

By: Jeffrey Benjamin, Esq.
5 Penn Plaza, 23rd Floor
New York, New York 10001
(212) 835-1532

TABLE OF CONTENTS -- BRIEF

	<i>Page</i>
TABLE OF AUTHORITIES	ii
I. INTRODUCTION	1
II. STANDARD OF REVIEW	2
III. THE SUBJECT ORDER	2
IV. ARGUMENT	3
A. The 9th Circuit Hemp Cases the Court Relied on Are Fatally Flawed.....	3
B. “Whole” Hemp, in Contrast to “Stalks and Seeds,” is a Controlled Substance.....	4
C. The science the hemp cases are based on, and the facts in this case, create material facts in dispute	5
D. Clutching At Stalks. The Difference Between Stalks and “Mature Stalks”	10
E. The Apparent Absence of Dispute.....	12
F. THC Limits in Hemp I and II	14
G. CBD — Except In Trace Amounts — is not Found in Exempt Parts.....	16
H. Dixie X is Illegal For Human Consumption.....	17
V. CONCLUSION	19

TABLE OF AUTHORITIES

Cases:

<i>Colucci v. Beth Israel Med. Ctr.</i> , 12-cv-3964 at 2. (2d Cir. August 17, 2013)	2
<i>Hemp Industries Assoc. v. DEA</i> , 333 F.3d 1082 (9th Cir. 2003) ("Hemp I")	<i>in passim</i>
<i>Hemp Industries Assoc. v. DEA</i> , 357 F.3d 1012 (2004) ("Hemp II")	<i>in passim</i>
<i>Williams v. Gentry</i> (D. Nev. 2020)	1, 8, 11, 15, 19

Statutes:

21 C.F.R. 1308.....	2, 3, 17, 18
21 U.S.C. 331-335.....	17
21 U.S.C. §801 et seq.....	16, 19
49 C.F.R. Part 40.....	7
49 C.F.R. Part 382.....	6

Rules:

Fed. R. Civ. P. Rule 60 (b)(1).....	1, 2
Fed. R. Civ. P. Rule 60 (b)(2).....	8
Fed. R. Civ. P. Rule 60 (b)(6).....	1

I. INTRODUCTION

With the trial of this matter some months away, this application by Plaintiff is made as a first Motion *in Limine* as it relates to evidence by Plaintiff that has been precluded by the Court in its decision of November 21, 2019. Namely, before that decision, Plaintiff sought to offer evidence at trial that the product Defendants sold to Plaintiff was a “Controlled Substance” as it is defined by the federal Controlled Substances Act, 21 C.F.R. 1308, *et seq.*

Plaintiff makes this motion under FRCP Rule 60(b)(1) and (2) i.e. mistake, inadvertence and/or newly discovered evidence, and under 60(b)(6) because the Court’s prior Decision is based on the two 9th Circuit *Hemp* cases. *Hemp Industries Assoc. v. DEA*, 333 F.3d 1082 (9th Cir.2003) (“*Hemp I*”) and 357 F.3d 1012 (2004) (“*Hemp II*”). It was respectfully a mistake for the Court to find the *Hemp* cases dispositive over Plaintiff’s claim that Defendant’s product was a controlled substance.

This motion is respectfully based upon the following grounds: (1) mistake or inadvertent omission of Plaintiff’s evidence; and (2) the Court’s application of the *Hemp* cases’ doctrine vis-a-vis new case law that might alter the conclusion reached by the court. Plaintiff respectfully requests that the Court vacate its ruling on that part of Plaintiff’s claim that Defendants’ product was a Controlled Substance and therefore violated the RICO statute in light of the following:

1. A 2020 Nevada District Court decision interpreting the *Hemp* doctrine, specifically the weight to be given to evidence of THC levels issued on June 18, 2020, *Williams v. Gentry*, 2020 U.S. Dist. Lexis 107564; 2020 WL 3302971, (D. Nev. June 18, 2020), (and attached hereto as Exhibit “1”);
2. Testimony of the Defendant’s science expert; and

3. A report published by the DEA, “*Clarification of the New Drug Code (7350) for Marijuana Extract*¹, explaining the science behind the scheduling of marijuana extracts², that Plaintiff. (Attached hereto as Exhibit “2”).
4. The Department of Transportation Press Release on Compliance dated February 18, 2020 (attached hereto as Exhibit “3”).

II. STANDARD OF REVIEW

FRCP 60(b)(1) authorizes a district court to undo or alter a final judgment based on, among other things, a “mistake.” Although there is a circuit split in the types of “mistakes” this subsection covers, the Second Circuit Court of Appeals held that “Rule 60(b)(1) allows for relief from judgment in cases of mistake, including legal errors made by the District Court.”(citations omitted). *Colucci v. Beth Israel Med. Ctr.*, 12-cv-3964 at 2. (2d Cir. August 17, 2013).

III. THE SUBJECT ORDER

Plaintiff is seeking relief from the Court’s November 21, 2019 Order which stated in part: “In their motions, both sides take issue with the Court’s ruling on whether “Dixie X Dew Drops” - the product at issue - constituted a controlled substance under the federal Controlled Substances Act (“CSA”).” ECF 124 at 2. The Court concluded:

“The Court’s prior order is modified insofar as Douglas Horn may now proceed with his RICO claim only to the extent it is premised on predicate acts of wire and mail fraud. He may not proceed with his claim on the theory that Dixie X is a controlled substance.” ECF 124 at 6.

¹ https://www.deadiversion.usdoj.gov/schedules/marijuana/m_extract_7350.html

² Effective January 13, 2017, the CSA was amended with a new drug code for marijuana extract, 21 CFR 1308 DEA 342. See Federal Register, Vol. 81, No. 240, December 14, 2016, Rules and Regulations.

The Defendant argued that “it was a genuine error for the Court to find that Dixie X contained ‘resin extract derived from the Cannabis sativa plant’. See ECF 97-1, at 1, (quoting from Order, ECF No. 88 at 24). The Court agreed:

“Given the apparent absence of dispute, the Court proceeded on the assumption that Dixie X’s CBD byproduct constituted a resin extracted from the mature stalk.” (ECF 124 at 4); “Accordingly, because Plaintiffs have not presented any evidence to show that Dixie X contains either synthetic THC or natural THC derived from marijuana—as the CSA defines that term—Plaintiffs cannot prove their RICO claim to the extent it is premised on the allegation that Dixie X is a controlled substance.” ECF 124 at 6.; “The problem with Plaintiffs ’argument is that it runs headlong into the Hemp cases, where the Ninth Circuit invalidated the very regulations on which Plaintiffs rely. See Hemp II, 357 F.3d at 1019 (permanently enjoining enforcement of the regulations). The court stated in no uncertain terms that those regulations “may not be enforced with respect to THC that is found within the parts of Cannabis plants that are excluded from the CSA’s definition of ‘marijuana ’ or that is not synthetic.” Id. at 1018. Accordingly, the mere presence of naturally occurring THC in a product does not render it a controlled substance so long as it is derived from an excepted part of the Cannabis sativa plant. See id. at 1018-19. ECF 124 at 5.

IV. ARGUMENT

A. *The 9th Circuit Hemp Cases the Court Relied on Are Inapplicable*

The 9th Circuit Hemp cases the court relied on were decided in 2003 (Hemp I) and 2004 (Hemp II). ¹ They voided the then 2003 DEA rule 21 C.F.R. 1308.11(d)(27). That rule was a DEA THC Scheduling regulation applicable to all products of the Cannabis plant and synthetic THC. That rule made the Defendants’ product a “Controlled Substance.” After the Hemp cases the DEA did not withdraw the rule and a version was in effect at the time the instant matter arose and is in effect in 2012 when this case arose. 21 C.F.R. 1308.11(d)(31).

¹ HIA v. DEA, 333 F3d 1082 (CA 92003); HIA v. DEA, 357 F3d 1012 (CA9 2004)

In 2012, when the instant case arose, the *Hemp* cases were not the controlling law in New York. But as they were in the 9th Circuit, this Court was respectfully not bound by them, and thus was free to decide based upon the science offered to the Court. The science alone of the instant case distinguishes the *Hemp* cases from the facts in this Horn case.

B. “Whole” Hemp, in Contrast to “Stalks and Seeds,” is a Controlled Substance

The Ninth Circuit’s *Hemp I* and *Hemp II* decisions³ are markedly distinct from the instant case on at least one critical point. With regard to the *Hemp* cases, there was no question that the subject products were exempt from the CSA’s definition of marijuana. Here, however, the issue of whether Defendants’ Dixie X “elixir” fits within that exception is heavily contested and is ardently contended that this matter is an issue of fact for jury determination. The *Hemp* Court held that the products at issue were non-psychoactive *because the THC could not be detectable in a drug test:*

“The non-psychoactive hemp in [Petitioner/Appellants’ products is derived from the “mature stalks” or is “oil and cake made from the seeds” of the *Cannabis* plant, and therefore fits within the plainly stated exception to the CSA definition of marijuana.”

Hemp II at 1018. The *Hemp* case products contained “sterilized hemp seeds and oil,” (*Hemp I* at 1085) and THC levels were “sufficiently low to prevent confirmed positives in urine drug-testing for marijuana...” (*Hemp II* at 1018). The *Hemp* petitioners challenged a new CSA rule banning natural THC fearing that it would “nullify” the explicit exemption for their hemp seed and oil products (*Hemp I* at 1090) since a “true zero” of THC in Petitioner’s hemp seed and oil products was “not achievable.” (at 1086).

³ *Hemp Industries Assoc. v. DEA*, 333 F.3d 1082 (9th Cir.2003) (“*Hemp I*”) and 357 F.3d 1012 (2004) (“*Hemp II*”)

Plaintiff has argued consistently that Dixie X is derived from *non-exempt* parts of the cannabis plant.

C. The science the Hemp cases and the evidence produced herein show material facts in dispute

Assuming the Court accepted the legal reasoning in the *Hemp* cases, the facts in this case are clearly distinguishable based on the scientific basis for which the Ninth Circuit decided the *Hemp* cases. The Ninth Circuit in 2003 and 2004 agreed that marijuana is illegal, but that some parts of the cannabis plant, such as the stalks that contain “non-psychoactive” THC, are “legal” and not controlled substances. Defendants in the instant case claim their products come from the stalks. (Declaration of Roy A. Mura, Para 11. July 17, 2019).

The *Hemp* cases are based on the 9th Circuits belief that there is “non-psychoactive” THC in hemp. The *Hemp* court defined “A “psychoactive” substance is one “affecting the mind or **behavior.**” *Merriam-Webster Dictionary.* (HIA v. DEA, 357 F3d 1012, at 1019 (Hemp II)

The legally constructed category of “non-psychoactive THC” combines the perceived harmlessness of hemp with the theory that, in tiny doses, THC is not only non-psychoactive but also it is not a controlled substance *per se* and is safe. To avoid this legal conundrum, the court was forced to create a biologically fictitious category of “non-psychoactive THC.” This term is used throughout both of the *Hemp* cases. This creates an impossible category unknown to science that THC can be without psychoactive properties.

As the case law bears out, hemp and marijuana both contain THC, albeit in different amounts. Small amounts of THC are non-psychoactive in the same manner as small amounts of alcohol - increased dosage provides increased intoxication. By analogy, with alcohol a few sips will not make a person dangerous but drink enough to fail an alcohol test and a person becomes

dangerous when driving a truck.² That is, danger comes from the psychoactive effects of alcohol.

In the instant case, there is no doubt that THC was present in the Defendants' product sent to Plaintiff. Their own Certificates of Analysis confirm the presence of a measurable amount as did the Plaintiff's independent test of the product at the EMSL lab. It is also indisputable that THC was present in Mr. Horn's body through the Department of Transportation's drug screening of him. The science basis in the *Hemp* cases upon which the Court relied for deciding that there was non-psychoactive THC was provided in *Hemp I* at page 185.

Mr. Horn tested positive on a federal Department of Transportation drug test. In 2012, the DOT cut off level for the presence of THC was 50 nanograms per milliliter (ng/mL) and 15 nanograms for the confirmation GC-MS.⁴ These same levels are mentioned in the above study that the 9th Circuit relied upon in the *Hemp* cases. And the levels are the same today. As such and according to *Hemp I*, Mr. Horn had psychoactive amounts of THC in his body.

DOT Drug Testing Rules Decide What Is Psychoactive THC for Truck Drivers

The federal Department of Transportation DOT has promulgated regulations that require THC testing of truck drivers under the Federal Highway Administration (FHWA) rule 49 C.F.R. 382. The DOT regulations use Department of Health and Human Services (HHS) mandatory guidelines for drug testing. They require chain of custody of specimens, quantified confirmation

² Roussella, Aaron, "The Forensic Identification of Marijuana: Suspicion, Moral Danger, and the Creation of Non-psychoactive THC, 22 Alb. L.J. Sci. & Tech. 103 (2012)

⁴ Cut-off levels are given in terms of the concentration of drug that can be measured in urine: either $\mu\text{g/mL}$ ("micrograms per milliliter"), which is one-millionth of a gram of drug in one-thousandth of a liter of urine; ng/mL ("nanograms per milliliter"), which is one-billionth of a gram of drug in one-thousandth of a liter of urine; or mg/dL ("milligrams per deciliter"), which is one-thousandth of a gram of drug in one-tenth of a liter of urine. If the concentration is less than the cutoff level, the test is considered negative.

of any positive screening result, collection of split samples of body fluid specimens, confidentiality of test results, and scientifically random selection of employees to be tested.

Under the DOT rules, drug testing is conducted by analyzing an employee's urine specimen. The analysis is performed at laboratories certified and monitored by the Department of Health and Human Services (HHS). 49 C.F.R. 40.

All urine specimens are analyzed for THC. The testing is a two-stage process. First, a screening test is performed. If it is positive for one or more of the drugs, then a confirmation test is performed for each identified drug using state-of-the-art gas chromatography/mass spectrometry (GC/MS) analysis. GC/MS confirmation ensures that over-the-counter medications or preparations are not reported as positive results. 49 C.F.R. 40.

All drug tests are reviewed and interpreted by a physician medical review officer (MRO) before they are reported to the employer. 49 C.F.R. 40. The DOT process is scientifically sound and has been upheld in multiple court decisions.⁵

The DOT has determined THC detection cut off levels. Under federal law anyone who has enough THC in his or her body to be detected above those levels is considered to be unsafe to drive a commercial motor vehicle and can be terminated, as was Mr. Horn. That amount of THC is “affecting the mind or **behavior**” and is psychoactive as defined by the 9th Circuit.

The *Hemp* cases also relied on this statement at *Hemp I* page 1089

The congressional hearings show that Congress was informed by some experts that hemp seed and oil contain small amounts of the active ingredient in marijuana, but that the active ingredient was not present in sufficient proportion to be harmful. Blue Brief at 17–22 (citing Hearings on H.R. 6385, 75th Cong., 1st Sess. 8 (April 1937); U.S. Senate Finance Committee, Hearings on H.R. 6906, 75th Cong., 1st Sess. 9 (1937)).

⁵ Evans, David G., Chapter 4, “Federal and State Testing Laws,” Drug Testing Law, Technology, and Practice, Thomson-Reuters, Rochester, NY (in print and on Westlaw)

Since the *Hemp* cases did not mention any other science on these points, we must assume that any product that tested positive on a drug test over the limits in the *Hemp* cases would be psychoactive or harmful. Mr. Horn had enough THC to be positive on a drug test and was considered “harmful” by the DOT as a driver on our highways.

Under FRCP 60(b)(2) and (6), and in addition to the *Williams v. Gentry* case, *infra*, the Court is respectfully pointed to Exhibit “4” hereto: the DOT Compliance Notice of February 18, 2020. This compliance notice can also be found at:

https://www.transportation.gov/sites/dot.gov/files/2020-02/ODAPC_CBD_Note.pdf. This Notice was the DOT’s recent warning to “safety-sensitive employees” such as Plaintiff here that among other things:

- a) The DOT requires testing for marijuana not CBD products;
- b) The labeling of many CBD products may be misleading because the products could contain higher levels of THC than what the product states;
- c) There is no federal oversight to ensure labels are accurate;
- d) The DOT acknowledged that taking a CBD product could lead to a positive drug test result.

Mr. Horn did not have the benefit of this 2020 warning as to Defendants’ product back in 2012 when Defendants marketed and sold their product to Plaintiff as having “no THC”, and he took it relying on their advertising and other statements. The fact remains that Plaintiff should be allowed to offer evidence at trial that the product was a controlled substance, based upon is own confirmatory drug test, the Defendants’ own Certificates of Analysis, corroborated by Plaintiff’s own independent lab testing of the product.

THC in CBD Products

In 2016, the Food and Drug Administration (FDA) tested the chemical content of cannabinoid compounds in CBD, and many were found to not contain the levels of CBD they claimed to contain and several contained amounts of THC way beyond anything that came from hemp.⁶

The Journal of the American Medical Association (JAMA) published a research letter showing the results of “undercover” purchases of CBD from Internet sources such as the Defendants’ products. Of 84 samples tested, THC was detected in 21%. This yielded a good deal of information suggesting that open-source CBD bought on the Internet is not a very reliable or safe product if one is planning to use it for medical purposes or in foods.⁷

A Johns Hopkins researcher reports that the vast majority of edible marijuana products sold in a sample of medical marijuana dispensaries carried labels that overstated or understated the amount of THC. The study collected 75 different products. Only 13 products were accurately labeled.⁸

A report published by the National Institute of Health showed that these products were mislabeled. THC was detected in 21% of samples. This study also notes that products containing THC could have sufficient enough concentrations to produce intoxication in children.⁹

⁶ Open the 2016 section <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>

⁷ <https://jamanetwork.com/journals/jama/article-abstract/2661569?redirect=true>

⁸ https://www.socialworktoday.com/news/dn_062315.shtml

⁹ Inadequate Regulation Contributes to Mislabeled Online Cannabidiol Products
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6024459/>

The Defendants in their advertising claimed that their products had no THC. Through the various summary judgment motions herein, that has proven to be false. They later claimed that their products come from stalks and there were no controlled substances in their products, yet, Mr. Horn tested positive. Despite their affidavits, a jury could reasonably conclude that based on the drug test that the product was indeed a controlled substance.

D. Clutching at Stalks – This was Hemp Whole Plant Extract. The Difference Between Stalks and “Mature Stalks”

Defendants never affirmatively assert, let alone prove, that only “mature stalks” go into its Elixir. Even the Defendant’s own scientific expert asserts this critical factor throughout hours of testimony on the methods of manufacture. The Defendants’ offer of proof in this regard consists solely of an unsupported statement by Defendant’s CEO, Stuart Titus—a denial and not an affirmation:

“[I]t is not even possible to extract “resin” from the stalks of hemp *Cannabis sativa* plants, which is undisputedly, the manner in which the CBD was extracted from the plants in order to formulate the Dixie X product.”

See ECF No. 97-1 at 4, quoting ECF No. 97-1 at 17. As argued, the manufacturers in *Hemp I* and *Hemp II* used only the “mature stalks” or the “oil and cake made from the seeds” of the *Cannabis* plant” (*Hemp II* 357 F.3d 1012 at 1018). In stark and significant contrast, the Defendants here do not assert that their extract incorporated only “mature” stalks of the plant, or “sterilized” seeds of the plant. On this point, Defendant’s own science expert (as argued more fully below) did not once use the words “mature” or “seed” during her deposition (ECF 61-9).

Perhaps most telling, the offending product is labeled by the Defendants as a “hemp whole plant extract.” The label on Defendants’ product was Exhibit #9 in Plaintiff’s Motion for Summary Judgment at Doc #.

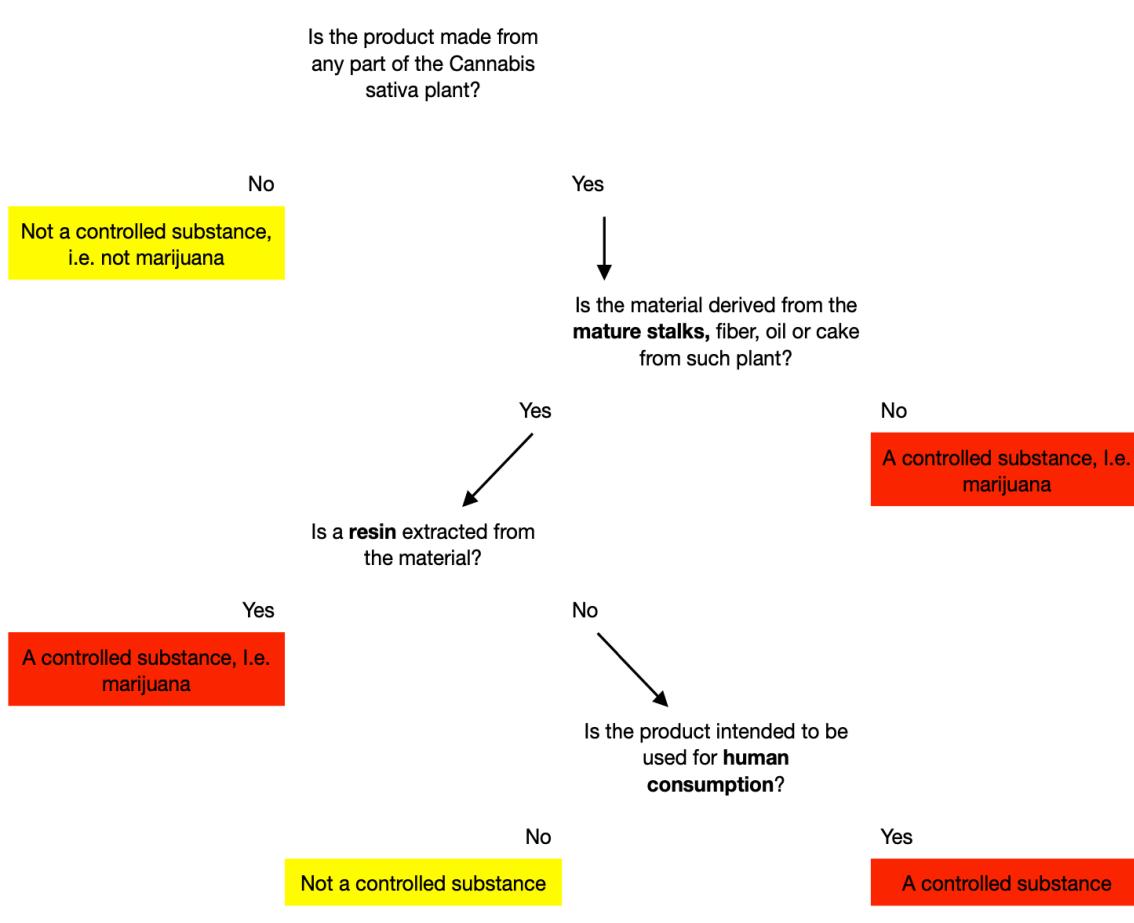
The significance of the difference between “mature stalks” and all “stalks” was the paramount consideration in *Williams v. Gentry*:

“The Counsel argued in the defense closing that there was no way to know that the marijuana and metabolite in the blood tests came from the “criminalized” rather than the “non-criminalized” portion of the marijuana plant. Similarly, with regard to stems, the statute expressly includes “all parts” of the Cannabis plant with a pertinent exception only for “mature” stems. The statute further refers to the capability of producing fiber from such stems, suggesting a fair amount of substantiality. There was no evidence in the record that any stems in the nearly one-third ounce of marijuana were “mature” stems, and the exclusionary language in the statute refers only to “mature” stems as against the general rule that “all parts” of the plant are included within the definition of “marijuana.” Viewing the evidence in the light most favorable to the prosecution, which again is what is required on Jackson review, a rational juror easily could have concluded on the evidence presented that any THC and/or marijuana metabolite measured in Williams’ bloodstream that arguably was attributable to stems was from a portion of the marijuana plant that constituted “marijuana” under N.R.S. 453.096.”

Williams v. Gentry at 75.

The record adduced throughout these proceedings provides no evidence at all that the stalks used to extract Dixie X were “mature” stalks. Clearly, whether or not the process utilized by the Defendants in the Dixie X extracts is a question of fact for the trier of fact.

The flowchart below shows the sequence of facts that logically needs to be established to arrive at the conclusion that a hemp derivative is not a controlled substance:



E. The Apparent Absence of Dispute.

It is respectfully contended that the Court erred in its focus and then determination that the “Plaintiffs have not presented any evidence to show that Dixie X contains either synthetic THC or natural THC derived from marijuana.” ECF 124 at 5. Plaintiff’s proffer affirmatively demonstrated that Dixie X is derived from *non-exempt* parts of the cannabis plant (i.e. marijuana). In fact, Dixie’s own label was emblazoned with the statement “hemp whole plant extract,” (ECF 112-3 at 3), and the Defendant’s own science expert, Dr. Cindy Orser, specifically described that the raw materials used to manufacture hemp extracts were produced in

various ways including: a resin extract; a hemp paste; an extract derived from medicinal hemp, the raw plant; and/or a very, very, very viscous, think honey, kind of material. Dr. Orser was quite clear when she testified on this point:

Q: So can you tell me generally what you know about other companies and how they turn a hemp product into a product like a tincture here?

A: There's an extraction step, so the most simplistic way is you take dried hemp and extract it with some solvent like ethanol. And then after it sits there for a while, you sieve out the gross plant material. So then you're left with the tincture, the ethanol extract.

ECF 61-8 at 79-80.

Plaintiff additionally argued that “two independent chemical analyses revealed that Dixie X contained THC” 1121-3 at 7. Dixie’s own CannLabs Testing Certificate, ECF 61-10, showed Dixie X having .05% of THC, or 500 parts per million (ppm)⁴, and .47 mg and .39 mg, or 470 ppm and 390 ppm⁵. These *far exceed* the THC levels in the Hemp cases. The *Hemp* case discussed trace amounts of “less than 2 ppm in the seed and 5 ppm in the oil.” *Hemp* I at 1085. Mr. Horn tested positive in a Department of Transportation (DOT) drug test with a cut-off level 50 ng/mL (nanograms per milliliter) (or .05 ppm)⁶ and 15 nanograms for the confirmation GC-MS. These are the same drug screen thresholds the 9th Circuit relied on in *Hemp* I and II. The levels are the same today. The GC-MS is same machine used in the toxicology study cited in *Hemp* I. Defendants’ science expert Dr. Orser confirmed that THC levels are “detectable” in Defendant’s own lab tests:

Q: However, those numbers indicate some of THC; right?

A: Detectable, even though right here if it’s below .1, it’s not detectable, even

⁴ .01% equals 100 ppm

⁵ 1 mg per gram equals 1,000 ppm

⁶ 1 ng/mL equals .001 ppm

though they're reporting it later.

Q: When you say reporting it later, are you talking about the .05 percent?

A: On the first page it says undetectable. It defines undetectable as below 0.1, but yet on the last two pages, they're reporting a value of less than .1. The .04 and .05 percent.

Q: So there is, at least with respect to the .05, a detectable amount of THC; correct?

A: It's being reported.

Q: And it doesn't say undetectable there; right?

A: Right.

Q: So that is some quantity of THC in at least these Certificates of Analysis?

A: Yes.

According to *Hemp I*, Mr. Horn had illegal amounts of THC in his body after consuming the Defendants' product.

F. THC Limits in Hemp I and II.

Even if Dixie X was derived from CSA-excludable portions of marijuana *only*, a supposition neither established nor conceded, the sale of Dixie X to the plaintiff was nonetheless unlawful. It is beyond dispute that Dixie X contained levels of THC that would cause a positive drug test. Whether levels of THC were detectable was the salient point that Ninth Circuit's *Hemp* decisions turned upon:

“Thus, because the DEA has failed to indicate any limit of detectable amounts for THC, the manufacture, distribution, and sale of hemp seed and oil products, which inevitably contain some trace THC, could prompt enforcement actions by the DEA. For this reason, petitioners have standing.” *Hemp I* at 1086.

In this regard, the District Court in Nevada, in *Williams v. Gentry* (D. Nev. 2020)⁷, deemed THC levels fundamental to a *Hemp* analysis:

“As the Ninth Circuit has explained, this statutory definition excludes portions of the Cannabis plant that (a) have other licit utility, while (b) having no more than “minuscule trace amounts of THC” that are insufficient to be psychoactive and show up in drug screens.” (Citing *Hemp Industries Assoc. v. DEA*, 357 F.3d 1012, 1013 & n.2, & 1018 (9th Cir. 2004) (Hemp II); *Hemp Industries Assoc. v. DEA*, 333 F.3d 1082, 1085 & 1088-89 (9th Cir. 2003) (Hemp I)).

Williams v. Gentry (D. Nev. 2020).

The *Williams* decision suggests that the hemp used to make Dixie X would only be exempted if it contained too little THC to even show up in drug screens, or “insufficient to be psychoactive and show up in drug screens”, *ibid.* at 65. The *Hemp I* decision cites extensively from a Journal of Analytical Toxicology study on THC levels:

“Tetrahydrocannabinols (“THC”) is the active ingredient in marijuana. Hemp seeds and oil typically contain minuscule trace amounts of THC, less than 2 parts per million in the seed and 5 parts per million in the oil. Enhanced analytical testing indicates that “a ‘THC Free ’status is not achievable in terms of a true zero.” Petitioner’s Reply on Emergency Motion for Stay, Exh. 2 Crew Dec. at 2. Nonetheless, the amount of trace THC present in hemp seed and oil is sufficiently low to prevent confirmed positives in urine drug testing for marijuana even from extended and extensive consumption of hemp foods. Leson, Pless, Grotenhermen, Kalant and ElSohly, “*Evaluating the Impact of Hemp Food Consumption on Workplace Drug Tests*,” 25 Journal of Analytical Toxicology 691 (Nov./Dec.2001).” *Hemp I* at 1085.⁸

⁷ Attached hereto as Exhibit 1.

⁸ The abstract of the above Leson report states:

Evaluating the Impact of Hemp Food Consumption on Workplace Drug Tests
G Leson 1, P Pless, F Grotenhermen, H Kalant, M A ElSohly

Affiliations expand

PMID: 11765026 DOI: 10.1093/jat/25.8.691

Abstract

Foods containing seeds or oil of the hemp plant (*Cannabis sativa L.*) are increasingly found in retail stores in the U.S. The presence of delta9-tetrahydrocannabinol (THC) in these foods has raised concern over their impact on the

G. CBD — Except in Trace Amounts — is not Found in Exempt Parts.

It has been shown scientifically that cannabinoids, including CBD, in the concentration necessary to make a product like Dixie X, are not found in the parts of cannabis that are exempted from the CSA definition of marijuana. The DEA in 2016 issued a Final Rule adding a drug code for marijuana extract on Schedule 1.⁹ The Final Rule did not add any substance to the schedules that was not already controlled, and did not change the schedule of any substance, it was not a scheduling action under 21 U.S.C. §§ 811 and 812. A DEA report clarifying the new drug code¹⁰ (attached hereto as Exhibit “2”) infers that the levels of THC —or CBD —in Dixie extract could not possibly come from *exempt* raw materials.:

“According to the scientific literature, cannabinoids are not found in the parts of the cannabis plant that are excluded from the CSA definition of marijuana, except for trace amounts (typically, only parts per million) that may be found where small quantities of resin adhere to the surface of seeds and mature stalk. Thus, based on the scientific literature, it is not practical to produce extracts that contain more than trace amounts of cannabinoids using only the parts of the cannabis plant that are excluded from the CSA definition of marijuana, such as oil from the seeds.” (citing H. Mölleken

results of workplace drug tests for marijuana. Previous studies have shown that eating hemp foods can cause screening and confirmed positive results in urine specimens. This study evaluated the impact of extended daily ingestion of THC via hemp oil on urine levels of its metabolite 11-nor-9-carboxy-delta9-tetrahydrocannabinol (THC-COOH) for four distinct daily THC doses. Doses were representative of THC levels now commonly found in hemp seed products and a range of conceivable daily consumption rates. Fifteen THC-naïve adults ingested, over four successive 10-day periods, single daily THC doses ranging from 0.09 to 0.6 mg. Subjects self-administered THC in 15-mL aliquots (20 mL for the 0.6-mg dose) of four different blends of hemp and canola oils. Urine specimens were collected prior to the first ingestion of oil, on days 9 and 10 of each of the four study periods, and 1 and 3 days after the last ingestion. All specimens were screened for cannabinoids by radioimmunoassay (Immunalysis Direct RIA Kit), confirmed for THC-COOH by gas chromatography-mass spectrometry (GC-MS), and analyzed for creatinine to identify dilute specimens. **None of the subjects who ingested daily doses of 0.45 mg of THC screened positive at the 50-ng/mL cutoff. At a daily THC dose of 0.6 mg, one specimen screened positive. The highest THC-COOH level found by GC-MS in any of the specimens was 5.2 ng/mL, well below the 15-ng/mL confirmation cutoff used in federal drug testing programs. A THC intake of 0.6 mg/day is equivalent to the consumption of approximately 125 mL of hemp oil containing 5 microg/g of THC or 300 g of hulled seeds at 2 microg/g. These THC concentrations are now typical in Canadian hemp seed products. Based on our findings, these concentrations appear to be sufficiently low to prevent confirmed positives from the extended and extensive consumption of hemp foods.** (Emphasis added) (Exhibit 4)

⁹ Federal Register Volume 81, Number 240 (Wednesday, December 14, 2016).

¹⁰ *Clarification of the New Drug Code (7350) for Marijuana Extract,*
https://www.deadiversion.usdoj.gov/schedules/marijuana/m_extract_7350.html

and H. Hussman. Cannabinoid in seed extracts of *Cannabis sativa* cultivars. *J. Int. Hemp Assoc.* 4(2): 73-79 (1997).

However, as indicated above, where a product, such as oil from cannabis seeds, consists solely of parts of the cannabis plant excluded from the CSA definition of marijuana, such product would not be included in the new drug code (7350) or in the drug code for marijuana (7360), even if it contained trace amounts of cannabinoids.

The key point to consider here is the fact that Dixie X contained **500 ppm** of THC as confirmed by its Certificates of Analysis. “Hemp seeds and oil typically contain minuscule trace amounts of THC, less than **2 ppm** in the seed and **5 ppm** in the oil.” *Hemp* I at 1085. Plaintiff should respectfully be allowed to present evidence that at very least allow for an inference from the trier of fact that the product was a controlled substance.

H. Dixie X is Illegal for Human Consumption

Lastly, even if Dixie X is exempt from the definition of “marijuana,” it cannot be used for human consumption *without FDA or DEA approval*. The *Hemp* decisions did not void the CSA law on this point. Dixie X is indisputably an elixir intended for oral consumption. *See* 21 U.S.C. 331-335; 21 C.F.R. 1308.35.¹¹

The defendants advertised their products to be used for human consumption. Under the CSA they bear the burden of proof that they have such an exemption for human consumption. Nowhere in the record to date have Defendants done so. The *Hemp* cases did not void the regulation regarding human consumption that was in place at that time. 21 C.F.R. 1308.35

¹¹ Source: Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency’s regulation of products containing cannabis and cannabis-derived compounds. [Https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm)

(2011) (creating an exception for cannabis material containing THC that is not included in the definition of “marijuana” and that is not intended for human consumption). This regulation governs any THC found in exempt hemp. If it has THC, it cannot be used for human consumption without approval.

21 C.F.R. § 1308.35

§ 1308.35 Exemption of certain cannabis plant material, and products made therefrom, that contain tetrahydrocannabinols.

- (a) Any processed plant material or animal feed mixture containing any amount of tetrahydrocannabinols (THC) that is both:
 - (1) Made from any portion of a plant of the genus Cannabis excluded from the definition of marijuana under the Act [i.e., the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination] and
 - (2) Not used, or intended for use, for human consumption, has been exempted by the Administrator from the application of the Act and this chapter.
- (b) As used in this section, the following terms shall have the meanings specified:
 - (1) The term processed plant material means cannabis plant material that has been subject to industrial processes, or mixed with other ingredients, such that it cannot readily be converted into any form that can be used for human consumption.
 - (2) The term animal feed mixture means sterilized cannabis seeds mixed with other ingredients (not derived from the cannabis plant) in a formulation that is designed, marketed, and distributed for animal consumption (and not for human consumption).
 - (3) The term used for human consumption means either:
 - (i) Ingested orally or
 - (ii) Applied by any means such that THC enters the human body.
 - (4) The term intended for use for human consumption means any of the following:
 - (i) Designed by the manufacturer for human consumption;
 - (ii) Marketed for human consumption; or
 - (iii) Distributed, exported, or imported, with the intent that it be used for human consumption.
- (c) In any proceeding arising under the Act or this chapter, the burden of going forward with the evidence that a material, compound, mixture, or preparation containing THC is exempt from control pursuant to this section shall be upon the person claiming such exemption, as set forth in section 515(a)(1) of the Act (21 U.S.C. 885(a)(1)).(emphasis added). In order to meet this burden with respect to a product or plant material that has not been expressly exempted from control by the Administrator pursuant to § 1308.23, the person claiming the exemption must present rigorous scientific evidence, including well-documented scientific studies by experts trained and qualified to evaluate the effects of drugs on humans. [66 FR 51544, Oct. 9,

2001; 68 FR 14119, March 21, 2003]; AUTHORITY: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

This means that even under the *Hemp* cases, any such “non-psychoactive” THC products meant for human consumption are regulated and must apply for exemption to be used for human consumption. The Defendants’ products have been subject to industrial processes to extract cannabinoids such as CBD. The Defendants’ affidavit of CEO Stuart Titus, PhD. states that they “extract” CBD from the stalks. (Affidavit of Stuart Titus July 12, 2019, par. 6.). The affidavit of Mr. Mura states the same at paragraph 11.

V. CONCLUSION

Given the evidence offered by Plaintiff in the original Summary Judgment motions and then subsequently when the Court dismissed that portion of Plaintiff’s RICO claim, and given the *Williams v. Gentry* case interpreting the *Hemp* cases, as well as the recent DOT warning clearly acknowledging the mislabeling by CBD companies, Plaintiff moves for relief from the November 21, 2019 Order. Defendants claimed that their product came from stalks and could not be a controlled substance, yet, Mr. Horn tested positive. A jury could reasonably conclude and the Court should respectfully permit Mr. Horn to proceed with proofs that Defendants’ product was a controlled substance under the CSA.

WHEREFORE, Plaintiffs respectfully request that the Court grant the instant motion and such other and further relief as the Court may deem just proper.

Dated: New York, New York
September 15, 2020

Respectfully Submitted,

BENJAMIN ♦ HART, P.C.

Attorneys for Plaintiff

Jeffrey Benjamin

By: Jeffrey Benjamin, Esq.
5 Penn Plaza, 23rd Floor
New York, NY 10001
(212) 835-1532